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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,433	09/24/2003	Jan Weber	10527-626001 / 02-369	2417

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/670,433	<b>Applicant(s)</b> WEBER ET AL.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 19-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/03, 1/04, 3/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I in the reply filed on 01 September 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of Group I has been treated as an election without traverse (MPEP § 818.03(a)) and the requirement is made FINAL. Claims 19-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

2. Applicants request Species II be redefined. The apparatus claims of Group I contain the following patentably distinct species:

- I. Species I depicted in Figure 2, wherein magnetic material coats the entire stent.
- II. Species II depicted in Figure 4, wherein magnetic material coats less than the entire stent.

Species II has been modified as requested by applicants, and applicants have submitted to elect such a species for examination.

3. Applicant's election with traverse of Species II in the reply filed on 01 September 2006 is acknowledged. The traversal is on the ground(s) that an incorrect characterization of the species has been made. This is not found persuasive because even with the new characterization, the species do not overlap in scope and are still

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considered distinct. Therefore, the requirement is still deemed proper and is therefore made FINAL.

***Specification***

4. The disclosure is objected to because of the following informalities: the serial number and filing date of the cited application have been omitted on page 9 of the disclosure. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Frayne et al. (Patent No. 6,361,759 B1).

Regarding claim 1, Frayne et al. disclose an implantable medical device (column 5, line 2) comprising a support structure (stent; column 5, line 2) formed such that magnetic field changes proximate the support structure are substantially unobstructed (via a signal enhancing magnetic coating; column 4, lines 60-64).

Regarding claim 7, the magnetic material disclosed is paramagnetic (column 4, lines 60-61).

Regarding claim 9, the magnetic material includes at least one of the materials claimed (e.g. gadolinium; column 6, lines 6-12).

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Regarding claim 10, it is inherent the tubular structure includes an end portion and it is inherent the magnetic material is applied to the end portion since it is applied to the entire structure in order to visualize the entire device (column 4, line 63).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 5-6, 12, 14, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhong et al. (Publication No. 2003/0100830 A1).

Regarding claims 1, 2, and 12, Zhong et al. disclose an implantable medical device (paragraph 22) comprising a support structure (stent; paragraph 68) formed such that magnetic field changes proximate the support structure is substantially unobstructed (via a magnetic coating; paragraphs 13 and 20). It is inherent that the stent disclosed forms a generally tubular structure since endovascular stents (paragraph 68) are generally tubular. Furthermore, Zhong et al. inherently disclose the implantable device may be made of a substantially non-magnetic material (e.g., superelastic shape memory alloys; paragraph 68), since it is disclosed that implantable devices are composed of materials that do not produce adequate signals for detection by MRI techniques (paragraph 8). Regarding claim 12, it is also noted that the applicant is invoking 112 6<sup>th</sup> paragraph, and as previously stated Zhong et al. disclose coating the

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tubular structure with magnetic material to render it visible during a MRI procedure (paragraphs 13 and 20).

Regarding claims 3, 5, and 6, the tubular structure disclosed may be made of a metals, metal alloys, polymeric materials, ceramics, composites of any such materials, and biodegradable materials (paragraph 68).

Regarding claims 14 and 16, the material disclosed is paramagnetic (paragraph 20), and it is at least one of the materials claimed (e.g., gadolinium; paragraph 20).

Regarding claims 17 and 18, it is inherent the tubular structure includes end portions. Furthermore, Zhong et al. disclose the entire surface of the tubular structure may be provided with magnetic coating (paragraph 52), therefore, it is inherent that the magnetic coating is applied to the end portions of the stent.

8. Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhong et al.

Zhong et al. disclose that in addition to covering the entire tubular structure, the magnetic coating may also be provided only on selected portions (paragraph 52) of the tubular structure. Therefore, it is inherent that the magnetic material may be applied only to the end portions. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the magnetic material only to the end portions in order to enhance the visibility thereof or to render such portions visible under MRI (paragraph 52).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al.

Zhong et al. disclose that ferromagnetic material is well known in the art for making devices visible under MRI. Applicant has not disclosed that a ferromagnetic material provides an advantage over paramagnetic material, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with ferromagnetic material because the function of the magnetic material is to act as a coating to render the device visible under MRI and it is well known in the art that ferromagnetic particles are useful for this purpose. Therefore, it would have been obvious to one of ordinary skill in the art

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at the time the invention was made to modify the magnetic material of Zhong et al. to obtain the invention as claimed in claims 8 and 15.

12. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al. in view of Klumb et al. (Patent No. 6,921,414 B2).

Zhong et al. disclose the device as described above, however, Zhong et al. do not disclose the specific metallic material claimed. Klumb et al. disclose a generally tubular structure (Figure 3, element 122) and unlike Zhong et al., Klumb et al. teach the device is made of at least one of the metallic materials claimed (e.g., Nitinol; column 1, line 52) so that the device can radially expand when it is deployed at the target site (lines 50-67). Therefore, to construct the device of Zhong et al. of Nitinol as taught by Klumb et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a device with self-expanding properties.

13. Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klumb et al. in view of Zhong et al.

Regarding claim 30, Klumb et al. disclose a support structure (Figure 7A, element 12) including a segment (the whole support structure) helically oriented about an axis of an elongated medical instrument (catheter 136). Klumb et al. do not disclose the material is at least one of those claimed and that magnetic material is applied to the segment. Zhong et al. teach the material is at least one of those claimed (e.g., ceramic; paragraph 68) and that magnetic material applied to the support structure (paragraphs 13 and 20) in order to render the device visible under MRI (paragraph 1). Therefore, to construct the device of Klumb et al. as taught by Zhong et al. would have been obvious



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to one of ordinary skill in the art at the time the invention was made in order to view the device under MRI during and/or after insertion.

Regarding claims 31 and 33, the material disclosed is paramagnetic (paragraph 20), and it is at least one of the materials claimed (e.g., gadolinium; paragraph 20).

Regarding claim 32, Klumb et al. in view of Zhong et al. disclose that ferromagnetic material is well known in the art for making devices visible under MRI. Applicant has not disclosed that a ferromagnetic material provides an advantage over paramagnetic material, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with ferromagnetic material because the function of the magnetic material is to act as a coating to render the device visible under MRI and it is well known in the art that ferromagnetic particles are useful for this purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the magnetic material of Klumb et al. in view of Zhong et al. to obtain the invention as claimed in claim 32.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson   
September 19, 2006

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER  
